REMARKS

This is a supplemental amendment filed in response to the personal interview with the Examiner held on November 13, 2006.

I. THE PROCEEDINGS OF THE EXAMINER'S INTERVIEW

During the Examiner's Interview the Examiner suggested that the current claims should be canceled and new claims should be filed in which there is a lower limit for the amount of bioactive glass in the preserved composition or added in the case of the method claim, the composition claims are limited to preserved cosmetic compositions, and the antibiotic of Greenspan and the silver ion of Shimono are excluded by defining the compositions of the bioactive glass with the more limited "consisting of" wording.

The above new claims have been drafted according to the Examiner's suggestion.

II. Anticipation Rejection based on Shimono, et al

Claims 10 to 14 and 21 to 24 were rejected under 35 U.S.C. 102 (b) as anticipated by U.S. Patent 5,290,544 to Shimono, et al.

Claims 10 to 14 and 21 to 24 have been canceled, obviating their rejection

as anticipated based on Shimono, et al.

Shimono, et al, do disclose a soluble glass, which contain silver, copper, or zinc ions, which are known for their preservative action. See column 1, lines 45 to 50; the examples in columns 3 to 5, and the claims, especially claim 1 of Shimono, et al.

The new composition claims and new method claims have been limited to use of bioactive glass particles that **consist of** from 40 to 60 percent by weight SiO_2, from 10 to 30 percent by weight CaO, from 10 to 35 percent by weight Na_2O, from 2 to 8 percent by weight P_2O_5, from 0 to 25 percent by weight of CaF_2, from 0 to 10 percent by weight B_2O_3, from 0 to 8 percent by weight of K_2O, and from 0 to 5 percent by weight MgO.

The applicants' definition of the composition of the bioactive glass particles in the main method claim 25 and the main composition claim 29 excludes the presence of any of the metal ions, especially silver ions, which are the required anti-microbial ingredients according to column 1 of Shimono, et al. Applicants' bioactive glass particles themselves provide the antibacterial action without the assistance of silver, copper, or zinc cations.

Furthermore Shimono, et al, does disclose that the soluble glass containing the silver, copper, or zinc cations may be a phosphate containing glass in column 1, line 55, but a phosphate glass is known to contain comparatively large amounts of phosphate. In contrast, the bioactive glass according to the present invention used in the applicants' claimed method and composition contains at most 8 % by weight P_2O_5.

The examples 2, 3, and 4 of Shimono, et al, which are phosphate glasses, contain more than 50 mol % P_2O_5. Thus Shimono, et al, do not anticipate the compositions and methods of the applicants' new claims 25 to 35 on the basis of examples 2, 3, and 4 of Shimono, et al.

For the foregoing reasons and because of the changes in the independent claims, it is respectfully submitted that new claims 25 to 35 should not be rejected under 35 U.S.C. 102 (b) as anticipated by Shimono, et al.

III. Obviousness Rejection based on Shimono, et al, and Greenspan

Claims 15 and 20 were rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of International Patent Application WO 98/11853 filed by Greenspan.

Claims 15 and 20 have been canceled, obviating their rejection. However the bioactive glass compositions recited in these claims appear in the new claims 25 and 29.

Greenspan only discloses a composition and a method for medical purposes, which can be considered a pharmaceutical composition, which is used to accelerate the healing of wounds or burns.

Applicants' are now claiming only cosmetic compositions, not pharmaceutical compositions and thus do not intend to claim the pharmaceutical or medical compositions disclosed by Greenspan. Greenspan admittedly discloses the glass compositions of claims 15 and 20, which are about the same

as the bioactive glass compositions employed in the applicants' claimed methods and claimed compositions of claims 25 to 35.

Greenspan discloses and claims compositions that necessarily include antibiotics as well as bioactive glass. Greenspan teaches that the antibiotics are an indispensable component of their pharmaceutical compositions and their treatment method. See claim 1 of Greenspan, which includes "at least one topical antibiotic". With respect to the method see claim 9 of Greenspan, which claims a method of applying the topical antibiotic and the bioactive glass.

It is respectfully submitted that Greenspan does not disclose or suggest preserving cosmetic compositions by adding a bioactive glass particulate with the glass composition described on pages 10 and 11 of Greenspan (and claimed in claim 2) to the cosmetic compositions. Greenspan only discloses treating wounds or burns with this bioactive glass particulate and an antibiotic.

Furthermore Greenspan does not disclose or suggest the amount ranges for the bioactive glass particles used in the claimed cosmetic compositions and claimed methods for preserving the cosmetic compositions.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

> "Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was

made by the applicant...Even when obviousness is based on as single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." ***In re Kotzab***, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141

Thus there is no disclosure or suggestion in Greenspan alone of the features and limitations of the new claims 25 to 35.

With respect to the reasoning in the final Office Action dated April 19, 2006, with regard to a combination of the disclosures in Shimono, et al, with Greenspan, it is respectfully submitted that this reasoning cannot be applied to the subject matter of new claims 25 to 35.

Shimono, et al, do not disclose preserving their compositions with bioactive glass particles or any compositions that include bioactive glass. The glass particulate disclosed in Shimono, et al, are described as "soluble glass" but not bioactive glass. The glass compositions of the soluble glass of Shimono, et al, do not correspond to the known compositions of bioactive glass, because e.g. the exemplary phosphate glasses in examples 2 to 4 contain too much phosphate, generally 50 mol % or more of phosphate. In bioactive glass the molar ratio of calcium to phosphorus must be greater than 2, i.e. sufficient to form a hydroxyapatite layer, as explained in the last half of page 3 of the applicants' originally filed specification. No glass compositions with ingredient amount ranges are disclosed in Shimono, et al. None of the exemplary glass compositions in Shimono, et al, have a molar ratio of calcium to phosphorus that

is greater than 2. The soluble glass of example 1 of Shimono, et al, does not include either phosphorus or calcium. Example 3 does not contain calcium. Example 2 discloses a composition with a molar ratio of calcium to phosphorus of less than 1. Example 4 discloses a glass composition with a molar ratio of calcium to phosphorus of about 1/3.

Furthermore the preservative mechanism of bioactive glass is known to be entirely different from the soluble glass of Shimono, et al. The action of the soluble glass of the reference is based on delivery of silver, copper, or zinc ions, which are not present in bioactive glass particles of claims 25 to 35. In contrast, bioactive glass will interact with biological materials such as proteins and compounds that make up microbial cell walls because of a high alkaline pH in the interstitial glass pace due to formation of the hydroxyapatite layer.

Thus one skilled in the art would not consider the soluble glass of Shimono to be a bioactive glass in the same sense as defined in the present application on page 3, especially as claimed in claims 25 to 35 above.

Then one skilled in the art would not view the bioactive glass disclosed on pages 11 and 12 of Greenspan and claimed in claim 2 of Greenspan as a potential substitute for the soluble glass of Shimono, et al. Greenspan also discloses that the mechanism of action of the bioactive glass in their compositions is entirely different the mechanism of action of the soluble glass of Shimono, et al. According to page 12, last 5 lines, of Greenspan the mechanism of action of their bioactive glass involves "precipitation of a calcium and phosphous" layer, i.e. formation of the hydoxyapatite layer.

Thus one skilled in the art would not find a hint or suggestion in Greenspan to replace the soluble glass particles of Shimono, et al, with the bioactive glass particles of claim 2 of Greenspan, because their microbial action is entirely different and one would not be able to predict or expect from the references that the cosmetic compositions of Shimono, et al, could be preserved without using the somewhat toxic metal ions of silver, copper, and/or zinc.

Thus there is a lack of suggestion in the art to replace the soluble glass of Shimono, et al, with the bioactive glass of Greenspan to obtain the claimed method of claims 25 to 28 and the claimed compositions of claims 29 to 35.

For the foregoing reasons and because of the changes in the independent claims, it is respectfully submitted that new claims 25 to 35 should not be rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of International Patent Application WO 98/11853 filed by Greenspan or over Greenspan alone.

IV. Obviousness Rejection based on Shimono and Various Scientific Journal Articles

Claims 16 to 19 were rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of Yamanaka, et al, Chem. Materials **4**(3), pp. 495-497 (1992); Wu, et al, Chem. Materials **5**(1), pp. 115 - 120 (1993); and Wang, et al., Anal. Chem. **65** (19), pp. 2671- 2675 (1993).

Claims 16 to 19 were canceled, obviating their rejection on this ground.

Shimono, et al, has been discussed in greater detail above and the discussion will not be repeated here. Shimono, et al, does not disclose use of a bioactive glass particulate to preserve a cosmetic composition.

The secondary references, Yamanaka, et al; Wu, et al; and Wang, et al, do not supply **the necessary hint or suggestion** of the added limitations in the new claims, namely that the bioactive glass particles in the composition include CaO and P_2O_5 in amounts such that a molar ratio of calcium to phosphorus is greater than 2 and a layer of hydroxyapatite forms on the surface of the particles in aqueous media. Also they do not suggest using the bioactive glass composition, e.g. of claim 2 of Greenspan to preserve a cosmetic composition.

These secondary references were only cited to suggest the refractive index limitation that is now present in dependent claim 35.

Thus a case of *prima facie* obviousness of claims 25 to 35 cannot be established by combination of the secondary references with Shimono, et al, since they do not suggest the important bioactive glass composition features of claims 25 to 35..

For the foregoing reasons it is respectfully submitted that new claims 25 to 35 should **not** be rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of Yamanaka, et al, Chem. Materials **4**(3), pp. 495-497 (1992); Wu, et al, Chem. Materials **5**(1), pp. 115 - 120 (1993); and Wang, et al., Anal. Chem. **65** (19), pp. 2671- 2675 (1993).

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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